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## NOTICE OF ALLOWANCE AND FEE(S) DUE

29200 7590 03/11/2010

K&L Gates LLP  
P.O. Box 1135  
Chicago, IL 60690-1135

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 03/11/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/738,446

12/16/2003

Thomas D. Kelly

5928R2US BX2009T02074

8102

TITLE OF INVENTION: MEDICAL FLUID THERAPY FLOW CONTROL SYSTEMS AND METHODS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	06/11/2010

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
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**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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29200 7590 03/11/2010

**K&L Gates LLP**  
P.O. Box 1135  
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## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/738,446 12/16/2003 Thomas D. Kelly 5928R2US BX2009T02074 8102

TITLE OF INVENTION: MEDICAL FLUID THERAPY FLOW CONTROL SYSTEMS AND METHODS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$1510 \$300 \$0 \$1810 06/11/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
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DEAK, LESLIE R 3761 604-004010

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

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This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,446	12/16/2003	Thomas D. Kelly	5928R2US BX2009T02074	8102
29200	7590	03/11/2010	EXAMINER	
K&L Gates LLP P.O. Box 1135 Chicago, IL 60690-1135			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 03/11/2010				

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 177 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 177 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/738,446	KELLY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	LESLIE R. DEAK	3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to after final amendment filed 21 January 2010.
2. ☒ The allowed claim(s) is/are 14-16, 18-24 and 26-38.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date ____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date ____     | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|  | 9. <input type="checkbox"/> Other ____.   |

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14-16, 19-20, 23, 33-35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of US 4,702,829 to Polaschegg et al.

In the specification and figures, Collins discloses the apparatus substantially as claimed by applicant. With regard to claims 14, 23, 29, 31, 33-35, 38 Collins discloses a hemodiafiltration apparatus comprising a medical fluid circuit 40, medical fluid supply 50, first pump 62 to supply medical fluid to filtration apparatus 10, second pump 44 operable to pull fluid from the filtering device, and isolating apparatus in the form of upstream and downstream valves 55, 372 (see FIG 1a, paragraphs 0037-0039). Collins further discloses that the apparatus comprises a substitution fluid filter 92 upstream of the blood filtering device 10 (via line 366), and a flowmeter 68 that is connected to at least outlet of the filter (See FIG 1a). The device further comprises a control unit 110 that uses control schemes to operate the valves and pumps (see paragraph 0042). The controller may operate to close valves 55, 372 in order to place the cartridge in isolation or bypass mode and command pump 62 to deliver a volume of substitute fluid to the patient (see paragraph 0045).

The control scheme disclosed by Collins uses a second, separate replacement fluid supply 300 to deliver a bolus volume to the patient. The Examiner notes, however, that the fluid in reservoir 300 originated in supply 50, which means that the reservoir 300 contains fluid from the first fluid supply. Collins merely uses an intermediate storage location 300 for fluid from supply 50. Accordingly, when in isolation mode, substitution pump 62 delivers a volume of fluid that was originally from fluid supply 50.

Collins fails to disclose that the substitution fluid filter 92 comprises an ultrafilter. However, Polaschegg discloses a medical fluid apparatus that comprises ultrafilters 44 and 78 in the medical fluid circuit upstream of the blood filtration device 12 in order to purify the ultrafiltrate in the event of bolus to a patient (see FIG, columns 5-6). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use an ultrafilter, as disclosed by Polaschegg, as the substitution fluid filter 92 disclosed by Collins in order to purify the fluid being sent to the patient, as taught by Polaschegg.

In the alternative to the Examiner's interpretation of the fluid sources as disclosed by Collins as presented above, it is the position of the Examiner that the source of the fluid delivered by the bolus is a matter of design choice on the part of the Applicant. Collins discloses that both reservoirs 50 and 300 comprise diasylate fluid, rendering the operation disclosed by Collins functionally equivalent to the operation claimed by Applicant. Applicant has not disclosed that using the same medical fluid supply for both filtration and bolus is for any particular purpose or solves any particular problem. (Arguments of counsel do not comprise objective evidence.) The process disclosed by

Collins is the functional equivalent of the process claimed by applicant. Accordingly, it is the position of the Examiner that merely providing a single source of fluid for filtration and bolus as disclosed by Applicant rather than separate sources, as disclosed by Collins, is not a patentable difference from the apparatus disclosed by the cited prior art.

With regard to claim 15, Collins discloses that the volume of fluid issued to the patient is a bolus volume issued to maintain proper patient fluid balance, meeting the limitations of the claims (see paragraph 0045).

With regard to claim 16, Collins discloses that the control scheme is programmed to receive user input before delivery of the bolus (see paragraph 0045).

With regard to claims 19 and 20, Collins discloses that the control scheme relies on input from various pressure and flow sensor devices (such as a blood flow sensor which corresponds to applicant's blood volume sensor) in delivery of the bolus volume (see paragraphs 0011, 0045).

With regard to claim 28, Collins discloses that the apparatus comprises a third pump 42 which is "operable" or "capable" to receive fluid from the tubing areas near isolating valves 55 and 372 and pump it to the rest of the circuit (see FIG 1a).

With regard to claim 36, Polaschegg illustrates that the medical fluid path is configured to deliver medical fluid to the extracorporeal circuit both upstream and downstream of the blood filtering device (see FIG).

3. Claims 21, 26, 27, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of US 4,702,829 to Polaschegg et al, further in view of US 5,932,103 to Kenley et al.

In the specification and figures, Collins and Polaschegg disclose the device substantially as claimed by applicant (see rejection above).

With regard to claims 21 and 26, the cited prior art fails to disclose that the bolus delivered to the patient comprises a rinseback volume delivered at the end of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines 14-20) that also uses dialysis fluid as a rinseback fluid that is communicated to the patient after the completion of therapy upon patient input as controlled by the valves, pumps, and optical sensors (see column 48, lines 1-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to program the system disclosed by the cited prior art to deliver a rinseback fluid to the patient after therapy, as disclosed by Kenley, in order to ensure all extracorporeal blood is returned to the patient.

With regard to claims 27 and 32, the cited prior art fails to disclose that the bolus delivered to the patient comprises a prime volume delivered at the beginning of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines 14-20) that also uses dialysis fluid as a priming fluid that is communicated through the circuit before therapy as controlled by the valves, pumps, and air detectors of the circuit (see column 47, line 50 to column 46, line 27).



***Response to Arguments***

4. Applicant's amendment and arguments filed 4 August 2009 have been entered and fully considered.

5. Applicant's arguments with respect to the rejection(s) of the pending claim(s) under 35 USC § 103(a) to Collins and various secondary references have been fully considered but are not persuasive.

6. Applicant argues that Collins fails to disclose that the substitution fluid filter is upstream of blood treatment device 10. However, when fluid is pushed from substitution filter 92 through valve 87 and lines 366 and 130 to the blood treatment device 10, the substitution filter is in an upstream position with relation to filter 10. Accordingly, it is the position of the Examiner that the combination of references properly suggest the limitations of the pending claims.

7. Applicant argues that Collins does not provide a "rinse outlet." However, while Applicant provides a description of the function of the rinse outlet in the specification, such a description does not amount to a special definition that distinguishes the instantly claimed rinse outlet from any other disclosed port. It is the position of the Examiner that the ports disclosed by Collins are capable of being used for rinsing, meeting the limitations of the claims.

8. Applicant further argues that Collins fails to disclose that flowmeter 68 is connected to substitution filter 92. However, flowmeter 68 is, in fact, connected to the filter via lines 64 and 360 (see Collins, FIG 1A).

9. Applicant argues that a biosensor as claimed by Applicant is very different than the flowmeter disclosed by Collins. The Examiner admits that this may be the case, but Applicant has provided no objective evidence that distinguishes a biosensor from the disclosed flowmeter. Applicant points to a dictionary definition that alleges that a biosensor is sensitive to a physical or chemical stimulus—a flow sensor is sensitive to the physical stimulus of flow past the device. Applicant does not provide a special definition of biosensor, and arguments of counsel do not comprise objective evidence. Accordingly, it is the position of the Examiner that Collins' flow meter meets the limitations of the biosensor disclosed and claimed by Applicant.

***Allowable Subject Matter***

10. Claims 17, 18, 22, 24, 25, 30, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

12. With regard to claims 17, 18, 24, and 25, the cited prior art teaches a medical fluid circuit with a blood filter, valves, and an ultrafilter, but does not teach a control scheme programmed to operate as claimed by Applicant.

13. With regard to claims 22 and 30, the cited prior art teaches a medical fluid circuit with a blood filter, valves, and an ultrafilter, but does not teach that the isolating

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apparatus comprises a three-way valve, along with the other steps and limitations of the claim.

14. With regard to claim 30, the cited prior art teaches a medical fluid circuit with a blood filter, valves, an ultrafilter, and a controller, but does not disclose or suggest that the controller is programmed to allow periodic flow from a rinse outlet of the ultrafilter to a drain, along with the other steps and limitations of the claim.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/  
Primary Examiner, Art Unit 3761  
13 October 2009